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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,170	07/18/2003	Dana A. Oliver	56444(71710_	2730
24536	7590	11/22/2005	EXAMINER	
GENZYME CORPORATION LEGAL DEPARTMENT 15 PLEASANT ST CONNECTOR FRAMINGHAM, MA 01701-9322			SHAFFER, RICHARD R	
			ART UNIT	PAPER NUMBER
			3733	

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/623,170

Applicant(s)

OLIVER, DANA A.

Examiner

Richard R. Shaffer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

The drawings are objected to because applicant failed to properly correct for the addition of drawings in her application in relation to Cummings et al (US Patent 6,322,563). On page 18, Figures 9b and 9c do not both disclose an ID and OD, rather it is 9a and 9b that do.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the fluid about the fastener must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

The abstract of the disclosure is objected to because it fails to focus on the point of novelty. This disclosure is a clear improvement over Cummings et al (US Patent 6,322,563) and should focus on what is different in this application compared to that patent. The difference to the examiner is that Cummings et al used a friction fit relationship for holding the tack within the cannula whereas applicant uses "capillary action." Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 9 recite the limitation "predetermined distance is defined between the surgical fastener and inner diameter of the cannula." Applicant intends this to mean the distance between the outer diameter of the fastener over the majority of the shaft to inner diameter of cannula. However, this could also be interpreted as the distance between the protrusions to the inner diameter of the cannula, thus making the claims indefinite. All dependent claims have been rejected for being dependent to an indefinite claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Cummings et al (US Patent 6,322,563).

Cummings et al clearly anticipates a bioabsorbable fastener assembly comprising an applicator including a loading tip, carrier assembly removably mounted within the loading tip, cannula having an inner and outer diameter, and a surgical fastener (and surface feature) disposed within the cannula.

In its broadest reasonable interpretation, the "friction fit" of Cummings et al is a "clearance fit" of applicant because the fastener was still capable of being fit within the cannula and thus had "clearance." As for the fluid being in communication with at least one positive surface feature, this is inherently the case with Cummings et al when

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considering surgery. Bodily fluids will excrete and be drawn into the device to fill any gaps present between the fastener and cannula.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 4, 5, 7, and 9-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings et al in view of *Using Parylene for Medical Substrate Coating* (<http://www.devicelink.com>).

The only differences present between applicants device and Cummings et al are a larger clearance between the tack and cannula and the use of a hydrophobic liquid. The website teaches that coatings for products including bone pins, prosthetic hardware, catheters, needles, medical probes, and various other implants are known in the art. Reasons include physical isolation from moisture, chemicals, and other substances; surface passivation; electrical insulation; tie-down of microscopic particles; and reduction of friction. It further goes on to say typical coatings are solvent-based liquid resins such as epoxies, silicones, acrylics, and urethanes and that these types of coatings exhibit liquid properties including: pooling, bridging between adjacent surfaces, and exhibiting meniscus forces. From applicant's own admission, the issue with Cummings et al's device was that friction may have been too great and not allowed for detachment of the tack in relation to the cannula. Thus it would have been obvious to

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one of ordinary skill in the art to have coated Cummings et al's device with a liquid such as silicone to in the least reduce friction, if not also protect the tack.

In regard to claims 4, 5, 7, 12, 13, and 15 due to the nature of the Cummings et al device becoming jammed, a more readily obvious design choice of increasing the clearance between the two components is known. Even children are able to realize if two parts are sticking together due to a friction fit, you can make one smaller than the other. Thus, the dimensions applicant has claimed are deemed obvious dimension optimizations in order to retain a fit between the components while avoiding over slippage. This task is well within the skill of one of ordinary skill in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on 7-5 (Mon-Fri, every other Fri off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Richard Shaffer

Richard Shaffer
November 17th, 2005

Pedro Philogene
PEDRO PHILOGENE
PRIMARY EXAMINER